

K964393

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SUMMARY OF SAFETY AND EFFECTIVENESS
CHASE RETROGRADE CARDIOPLEGIA CANNULA

I. General Information

- A. Generic Name: Retrograde Cardioplegia Cannula
- B. Trade Name of Device: CHASE Retrograde Cardioplegia Cannula
- C. Applicant's Name and Address: CHASE Medical Inc.
1876 Firman Drive.
Richardson, Texas 75081
- D. Pre-market Notification Number: Not yet assigned

II. Indications for Use

The Chase Retrograde Cardioplegia Cannula is intended for use in perfusing blood or cardioplegia solutions via the coronary sinus during cardiopulmonary bypass surgery.

III. Device Description

The Chase Retrograde Cardioplegia Cannula is a dual lumen 14 FR cannula. The cannula body contains a primary lumen for infusing blood or cardioplegia solutions and a secondary pressure monitoring lumen that begins at the cannula's tip and terminates in a stopcock with a female luer lock. During infusions, differential pressures occurring within the cannula automatically inflate a soft, low pressure balloon located near the cannula's distal tip. When flow ceases, the balloon spontaneously deflates. A stylet is also provided to aid transatrial cannula placement within the coronary sinus.

IV. Device Classification: Class II

V. Safety and Effectiveness

Substantial Equivalence: The device is substantially equivalent to the Research Medical Retrograde Cardioplegia Cannula (K880103).

VI. Other Safety and Effectiveness Data

Materials: All material are identical to the predicate device.

Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL 10^{-6}

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Functional Testing

All functional characteristics of the Chase Retrograde Cardioplegia Cannula are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

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| Leak Test Requirements: | No leaks at 10 psi air on CHASE device at 4°C and 40°C |
| Tubing Bond Strength: | Exceeds 10 lb. tensile strength @ 4°C and 40°C |
| Luer Connections: | Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Tape Fittings |
| Package Integrity: | Tyvek/Polymylar passed burst test per ASTM F1140-88 |
| Shipping & Distribution Testing: | Per National Safe Transit Ass. vibration and drop tests |
| Accelerated Aging: | Two year shelf life |